K090085

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information

Trade Name	Merci® Retriever
Common Name	Endovascular Retriever
Classification	Thrombus Retriever, 21CFR 870.1250 – Class II

Submitter: Concentric® Medical, Inc.
301 E. Evelyn Avenue
Mountain View, CA 94041
Tel 650-938-2100
Fax 650-938-2700

FEB 12 2009

Contact: Laraine Pangelina
Director, Regulatory Affairs

Intended Use

The intended use for the modified Merci Retrievers is the same as the intended use of the predicate Merci Retrievers:

The Merci® Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. Patients who are ineligible for treatment with intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. The Merci Retriever is also indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.

Predicate Device

Merci® Retrievers (K063774, K062046 K071172, K070521, K081305, K082034)

Device Description

Like the predicate devices, the design of the modified Merci Retrievers consists of a flexible, tapered Nitinol core wire. This distal end is shaped into a helix and a platinum coil is threaded over and attached to the distal end. Polymer filaments are attached to the distal end. The core wire proximal to the helix is coated with a hydrophilic coating. A torque device is provided with Retriever to facilitate manipulation. An insertion tool is provided with Retriever to introduce Retriever into Microcatheter during the procedure. Merci Retrievers with "DOC® Compatible" shown on product label are compatible with the Abbott Vascular DOC® Guide Wire Extension.

Materials

The materials used in the modified Merci Retrievers are the same as the materials used in the predicate devices.

All materials used in the manufacture of the modified Merci Retrievers are suitable for the intended use of the device and have been used in numerous previously cleared products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Concentric® Medical, Inc.
% Ms. Laraine Pangelina
Director, Regulatory Affairs
301 E. Evelyn Avenue
Mountain View, California 94041

FEB 12 2009

Re: K090085
Trade/Device Name: Merci Retriever
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: NRY
Dated: January 12, 2009
Received: January 13, 2009

Dear Ms. Pangelina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson for
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): This application

Device Name: **Merci Retriever**

Indications for Use: The Merci® Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. Patients who are ineligible for treatment with intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. The Merci Retriever is also indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.

Prescription Use _X_ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090085